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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/645,847 Filing Date: August 22, 2003 Appellant(s): KLUNK ET AL.

> Steven M. Reid For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 6/19/08 appealing from the Office action mailed 10/18/07.

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(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

US Patent No. 7,270,800 KLUNK ET AL.

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(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 4 of U.S. Patent No. 7,270,800. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to products having a radiolabeled halogen. The claims differ in that those of the patented invention do not limit the location of the radiolabeled halogen. However, a skilled artisan would recognize that since both sets of claims require a radioisotope (i.e., radiohalogen) and the radioisotopes of the patented invention are not limited to any particular location, the skilled artisan would recognize that it is within the skill of an ordinary practitioner in the art to have a radioactive halogen at position R2 because Compounds 4, 8, 12, 16, 20, and 39 of the patented invention all contain a halogen in the R2 position and fulfill the requirements of the other variables (R1, R3, and R4) of the instant invention. Specifically, the skilled artisan would recognize that since the patented claims disclose that the radioisotope is selected from the group 131I, 125I, 123I, 18F, or 19F and the instant invention allows for R2 to be a radiohalogen at position R2, the claims contain overlapping subject matter. Below are the structures of Compounds 4, 8, 12, 16, 20, and 39 from US Patent No. 7,270,800.

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Compound 4:

Compound 8:

Compound 12:

Compound 16:

Compound 20:

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Compound 39:

(10) Response to Argument

In summary, Appellant makes the following assertions. (1) The double patenting rejection should be withdrawn because the issuance of claim 1 would not manifest an improper timewise extension of US Patent No. 7,279,800 because the claimed compounds are not obvious variants of patented claim 4. In addition, Appellant asserts that since the instant application is the later filed application, only a one way determination of obviousness is needed in resolving the issue of double patenting. (2) Appellant asserts that the patented invention does not specify in which position the radiohalogen is on the recited benzothiazole compound. (3) Appellant asserts that the Examiner has used improper hindsight in determining that the radioisotope is in the R2 position.

In response to Appellant's assertion regarding withdrawal of the double patenting rejection because the instant application is the later filed application and the issuance of claim 1 would not manifest an improper timewise extension of US Patent No. 7,279,800, Appellant's attention is directed to MPEP 804 (see excerpt below). MPEP 804 discloses the actions an Examiner should take when the obviousness type double patenting rejection is the only rejection remaining in the later filed application.

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MPEP 804: Nonstatutory Double Patenting Rejections

"If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later-filed application, while the earlier-filed application is rejectable on other grounds, a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn.

If "provisional" ODP rejections in two applications are the only rejections remaining in those applications, the examiner should withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without need of a terminal disclaimer. A terminal disclaimer must be required in the later-filed application before the ODP rejection can be withdrawn and the application permitted to issue".

It should be noted that in the office action mailed 10/18/07 the provisional rejection over Serial No. 10/388,173 (now US Patent No. 7,270,800) was replaced with a non-provisional double patenting rejection because Serial No. 10/388,173 had issued as a patent. Accordingly, while a portion of MPEP 804 (see excerpt above) discloses how the Examiner handles an application when only a 'provisional' non-statutory

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obviousness type double patenting rejection remains in the application, since the earlier application has issued as a patent, a terminal disclaimer is required for the later filed application in order to overcome the non-statutory obviousness type double patenting rejection.

In regards to whether or not the applications contain overlapping subject matter. the Examiner once again sets forth that patented Compounds 4, 8, 12, 16, 20, and 39 fall within the scope of Formula I in the instant invention (see claim 1). All of those compounds, like the instant invention, have halogens in the R2 position as required by instant claim 1. The obviousness of having a radiolabeled halogen in that position stems from the fact that the patented claim (see claim 4) discloses that at least one atom in the formula is replaced with a radiolabeled halogen such as 1311, 1251, or 123 halogen, for example. Both the compounds of the patented invention and the instant invention are used for the same purposes (i.e., imaging amyloid plagues). Hence, recognizing that imaging involves an atom/element that emits a signal (i.e., radioisotope) and the fact that both inventions disclose halogens in the R2 position, the replacement of a non-radioactive halogen with a radioactive halogen would be obvious since the compounds are being used for imaging purposes. Furthermore, while Appellant's specification is not used to limit the claims, review of column 33, the fifth and seventh structures (see below)

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$$\begin{array}{c|c} & \text{HO} & \text{NH}_2 \\ & \text{And} & \text{NH}_2 \\ \end{array}$$

both illustrate that the patented invention does not exclude radiohalogens in the R2 position.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In particular, hindsight was not used in determining whether or not the inventions contain overlapping subject matter. Specifically, both inventions are used for the same purpose (i.e., detecting amyloid plaques) and both the instant invention and patented invention disclose compounds having radiohalogens in the R2 position.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer. Application/Control Number: 10/645,847 Page 10

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/D. L. Jones/ Primary Examiner Art Unit 1618

Conferees:

/Michael G. Hartley/ Supervisory Patent Examiner, Art Unit 1618

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